

REMARKS

Reconsideration of the present application is requested. Applicant appreciates the indication of allowance of claims 54-65 and 69-72. Claims 34-40, 42-47, 49, 51-53 and 80-96 again stand rejected.

Claims 34-40, 42-47, 49, 51-53 and 80-92 had been previously indicated to be allowable, but this indication of allowability was withdrawn in the prior Office Action in favor of an anticipation rejection based on U.S. Patent No. 6,506,214 to Gross. Applicants' arguments with respect to these rejections were deemed persuasive and new grounds for rejection was issued. These claims (as well as previously added claims 93-96) were then rejected as anticipated under 35 U.S.C. 102(b) by U.S. Patent No. 6,740,093 to Hocschuler et al.

It is well-decided that anticipation requires that the cited reference disclose each and every feature of the claimed invention either explicitly or inherently. See, *Eli Lilly & Co. v. Zenith Goldline Pharm., Inc.*, 471 F.3d 1369, 1375, 81 U.S.P.Q.2d 1324 (Fed. Cir. 2006). The citation of the '093 Patent is fundamentally flawed because this reference only discloses a method and apparatus for treating a vertebral body, not a disc space, which the space between vertebral bodies. See, col. 1, ll. 16-18, 64-67. Moreover, the fluent material disclosed in the '093 Patent is intended to replace bone within a damaged vertebral body to stabilize the body and restore its height. See, col. 3, ll. 41-55. The material itself is, by necessity, a hardenable "bone filler" so that the resulting permanent implant will behave like bone. See, col. 6, l. 63 – col. 7, l. 7.

The '093 Patent does not disclose a curable fluent material that upon curing has "properties substitutive of the nucleus pulposus," as required in each of the independent claims 45, 80 and 92. It is well-known that a disc nucleus must elastically compress and restore as the spine is bent forward and backward. It is also well-known that the disc nucleus pulposus must be capable of absorbing vertical and transverse loads, as well as torsional loads, along the spine, acting as a multiple degree of freedom shock absorber.

On the other hand, the vertebral body is made of bone and is a rigid body. Thus, any fluent material introduced into the vertebral body as disclosed in the '093 Patent must be capable of similar rigidity. Certainly, any material that has "properties substitutive of

the nucleus pulposus" is not fit for use within the vertebral body. Introducing such a material into the vertebral bodies would mean that not only the discs but also the vertebral bodies themselves would be compressible and elastic in multiple degrees of freedom. It is not difficult to imagine that introducing an elastically compressible material where rigid bone is supposed to be would virtually destroy the function of the patient's spine.

The Hochschuler '093 Patent cannot anticipate any of Applicants' claims because it fails to disclose every limitation in those claims. The '093 Patent discloses methods and apparatus for treatment of the vertebral bodies, not the disc space. The '093 Patent discloses fluent material that is substitutive of the bone of the vertebral bodies, not substitutive of the properties of the nucleus pulposus. In addition, with respect to claims 45 and 92, there is also no disclosure of creating an opening in the disc annulus – the '093 Patent only discloses accessing the bone of the vertebral body. Thus, the '093 Patent also fails to disclose introducing the curable biomaterial into the intradiscal space, as required by claim 45, or "in contiguity with the annulus fibrosus" as required by claim 92.

With respect to claim 80, the '093 Patent also fails to disclose a tube having a seal adapted to engage the annulus fibrosus. The septum 82 identified in the Office Action is internal between the tube and an expandable container. See, col. 6, ll. 37-42. The septum is completely internal so that it can be punctured by a fill needle 84, so even if the tube of the '093 Patent is extended through a disc annulus, the septum still will not "engage said annulus fibrosus" as required by claim 80.

Since the '093 Patent only discloses repairing and restoring the vertebral body, there is no suggestion to modify the procedure and materials to treat the disc space. The two issues are very different – the vertebral body requires a rigid, solid replacement in order to maintain proper functioning of the spine, while the disc space requires an elastically deformable material to maintain the proper load-bearing capabilities for the spine.

In view of the foregoing arguments it is believed that the rejection of claims 34-40, 42-47, 49, 51-53 and 80-96 has been traversed. Therefore, it is requested that these rejections be withdrawn and that action be taken toward a Notice of Allowance.

Respectfully submitted,

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